K090366

APR 22 2009

Section 5
510(k) Summary

Section 807.92(a)

(1) Submitter

Source Production & Equipment Co., Inc.
113 Teal Street
St. Rose, LA 70087

Tel: 504.464.9471
Fax: 504.467.7685

Establishment Registration No.: 1000437833

Contact Person: John J. Munro III
Vice President
e-mail: johnm@spec150.com

(2) Device Name:

Classification Name: Radionuclide Brachytherapy Source (892.5730) (90 KXK)

Common or Usual Name: Brachytherapy Source

Proprietary Name: SPEC Model M-31

(3) Legally Marketed Predicate Devices:

Implant Sciences I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed), cleared under 510(k) number K994317 dated 21 March 2000, and

Implant Sciences Corp. HDR 4140 ^{169}Ytterbium High Dose Rate Brachytherapy Source, cleared under 510(k) number K042864 dated 06 January 2005

(4) Description of SPEC Model M-31 ^{169}Ytterbium Brachytherapy Source:

SPEC Model M-31 is a singly-encapsulated ^{169}Ytterbium Brachytherapy Source. It consists of a titanium capsule containing a solid radioactive ^{169}Ytterbium pellet. The capsule which contains the pellet consists of a titanium tube which is closed on each end with titanium wires which are laser-welded to the tubing.

(5) Intended Use

The intended use of SPEC Model M-31 Brachytherapy Source is for the treatment of cancer by temporary or permanent interstitial, intracavitary, intraluminal or intraoperative implantation or surface application.

(6) Technological Characteristics:

SPEC Model M-31 ^{169}Ytterbium Brachytherapy Source is similar to the predicate low dose rate brachytherapy source and utilizes photons from ^{169}Ytterbium.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2009

John J. Munro III, Ph.D.
Vice President
Source Production & Equipment Co., Inc.
113 Teal Street
ST. ROSE LA 70087

Re: K090366
Trade/Device Name: Model M-31 ^{169}Ytterbium Brachytherapy Source
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: April 14, 2009
Received: April 16, 2009

Dear Dr. Munro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

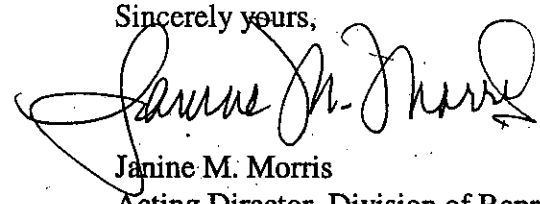
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K090366

Device Name:

Source Production & Equipment Co., Inc. Model M-31 ^{169}Ytterbium Brachytherapy Source

Indications for Use:

Source Production & Equipment Co., Inc. (SPEC) Model M-31 ^{169}Ytterbium Brachytherapy Sources, with individual activities up to 5 mCi (185 MBq), are indicated for temporary or permanent interstitial, intracavitary, intraluminal or intraoperative implantation or surface application to treat selected localized tumors. They can be used either as primary treatment for unresectable tumors, or as treatment for residual disease after excision of primary or recurrent tumors such as for lung cancer. Model M-31 Brachytherapy Source may be used concurrently with or following treatment with other interventions, such as external beam therapy, or chemotherapy. Tumors of the head, neck, lung, pancreas, prostate, breast and other accessible tumors are commonly treated.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090366

(Optional Format 1-2-96)